

## Appendices

### 510(k) Summary (Appendix A)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K984011.

#### 1. Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.  
100 Indigo Creek Drive  
Rochester, New York 14626-5101  
(716) 453-3607

Contact Person: Anne Zavertnik

Date 510(k) prepared: November 9, 1998

#### 2. Device Name

Trade or Proprietary Name: VITROS Immunodiagnostic Products Cortisol Range Verifiers. ±  
Common Name: Range Verifiers  
Classification Name: VITROS Range verifiers for use in verifying the calibration range of the VITROS Immunodiagnostic System, when used for the measurement of immunoassays which include Cortisol.

#### 3. Predicate Device

The VITROS Immunodiagnostic Products Cortisol Range Verifiers are substantially equivalent to VITROS Immunodiagnostic Products FSH Range Verifiers (K973517).

#### 4. Device Description

The VITROS Immunodiagnostic System uses luminescence as the signal in the quantitative and semi-quantitative determination of selected analytes in human body fluids, commonly serum, plasma and urine. Coated microwells are used as the solid phase separation system.

The system is comprised of three main elements:

1. The VITROS Immunodiagnostic Products (in this case VITROS Immunodiagnostic Products Reagent Pack, VITROS Immunodiagnostic Products Calibrators, which are combined by the VITROS Immunodiagnostic System to perform a VITROS assay).

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## 510(k) Summary (Appendix A), Continued

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2. The VITROS Immunodiagnostic System - instrumentation, which provides automated use of the immunoassay kits. The VITROS Immunodiagnostic System was cleared for market by a separate 510(k) pre-market notification (K962919).
3. Common reagents used by the VITROS System in each assay. The VITROS Immunodiagnostic Products Signal Reagent and VITROS Immunodiagnostic Products Universal Wash Reagent were cleared as part of the VITROS Immunodiagnostic Products Total T3 510(k) pre-market notification (K984310).

The VITROS System and common reagents are dedicated specifically only for use with the VITROS Immunodiagnostic Products range of immunoassay products.

### 5. Device Intended Use

For *in vitro* use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of immunoassays, which include Cortisol.

### 6. Comparison to Predicate Device

The VITROS Immunodiagnostic Products Range Verifiers are substantially equivalent to VITROS FSH Range Verifiers (predicate device), which was approved by FDA (K973517) for IVD use.

Table 1 lists the similarities and differences of the device characteristics between the VITROS Cortisol Range Verifiers with the predicate device, VITROS FSH Range Verifiers.

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## 510(k) Summary (Appendix A), Continued

**Table 1** List of the assay characteristics

| <b>Device<br/>Characteristic</b> | <b>VITROS CORTISOL<br/>Range Verifiers</b>   | <b>Predicate<br/>Device</b>  |
|----------------------------------|--|--|
| Intended use                     | For use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of a particular analyte (Cortisol). | For use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of FSH. |
| Matrix of Range Verifiers        | A base matrix of freeze-dried human plasma spiked with analyte (Cortisol).   | A base matrix of freeze-dried human plasma spiked with human pituitary FSH.  |
| Range Verifier levels            | Low and high   | Low and high   |

### 7. Conclusions

The information presented in the pre-market notification demonstrate that the VITROS Cortisol Range Verifiers are substantially equivalent to the predicate device, for which there is FDA clearance.

Equivalence was demonstrated by comparing the physical properties and intended uses of these devices with commercially available reagents.

The information presented in the premarket notification provide a reasonable assurance that the VITROS Cortisol Range Verifiers are safe and effective for the stated intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 7 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Anne Zavertnik  
Regulatory Affairs Associate  
Ortho-Clinical Diagnostics, Inc.  
100 Indigo Creek Drive  
Rochester, New York 14626-5101

Re: K984011  
Trade Name: VITROS Immunodiagnostic Products Cortisol Range  
Verifiers  
Regulatory Class: I  
Product Code: JJX  
Dated: November 9, 1998  
Received: November 10, 1998

Dear Ms. Zavertnik:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

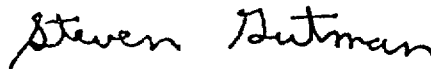
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large, stylized 'S' and 'G'.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Statement of Intended Use (Appendix C)

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510(k) Number (if known):


K 984011

Device Name:

VITROS Immunodiagnostic Products Cortisol Range Verifiers

Indications for Use:

For *in vitro* use in verifying the calibration range of the VITROS Immunodiagnostic System, when used for the measurement of immunoassays which include Cortisol.

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K 98 4011

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE  
IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)